

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/)	
FENFLURAMINE/DEXFENFLURAMINE))	MDL NO. 1203
PRODUCTS LIABILITY LITIGATION)	
)	
)	
THIS DOCUMENT RELATES TO:)	
)	
SHEILA BROWN, et al.)	CIVIL ACTION NO. 99-20593
v.)	
)	
AMERICAN HOME PRODUCTS)	2:16 MD 1203
CORPORATION)	

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO.

Bartle, C.J.

June 26, 2009

Kristi R. Saul ("Ms. Saul" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,¹ seeks benefits from the AHP Settlement Trust ("Trust"). Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").²

1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did

(continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. Part I of the Green Form is to be completed by the claimant or the claimant's representative. Part II is to be completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, Part III is to be completed by the claimant's attorney if he or she is represented.

In October 2002, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Douglas R. Smith, M.D. Based on an echocardiogram dated May 31, 2002, Dr. Smith attested in Part II of Ms. Saul's Green Form that she suffered from moderate mitral regurgitation and an abnormal left atrial dimension.³ Based on such findings, claimant would be

2 (...continued)

not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period, or who took the drugs for 60 days or less, or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these diet drugs.

3. Dr. Smith also attested that Ms. Saul had moderate aortic regurgitation. As Ms. Saul's claim does not present any of the complicating factors necessary to receive Matrix Benefits for damage to her aortic valve, her level of aortic regurgitation is not relevant to this claim. See Settlement Agreement § IV.B.2.c.(2) (a).

entitled to Matrix A-1, Level II Benefits in the amount of \$648,743.⁴

In the report of claimant's echocardiogram, Dr. Smith stated that Ms. Saul's "RJA/LAA equals 29%." Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA") in any apical view is equal to or greater than 20% of the Left Atrial Area ("LAA"). See Settlement Agreement § I.22. Dr. Smith also stated that "[l]eft atrial enlargement is present," which he measured as 6.3 cm in the supero-inferior systolic dimension and 4.1 cm in the antero-posterior systolic dimension. The Settlement Agreement defines an abnormal left atrial dimension as a left atrial supero-inferior systolic dimension greater than 5.3 cm in the apical four chamber view or a left atrial antero-posterior systolic dimension greater than 4.0 cm in the parasternal long-axis view. See id.

§ IV.B.2.c.(2) (b).

In February, 2004, the Trust forwarded the claim for review by Nancy V. Strahan, M.D., one of its auditing cardiologists. In audit, Dr. Strahan concluded that there was no

4. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2) (b). As the Trust did not contest the attesting physician's finding of an abnormal left atrial dimension, which is one of the conditions needed to qualify for a Level II mitral valve claim, the only issue is claimant's level of mitral regurgitation.

reasonable medical basis for the attesting physician's finding of moderate mitral regurgitation. Specifically, Dr. Strahan stated that:

I planimetered several [mitral regurgitant] jets in the [apical four chamber] views and the highest ratio I was able to obtain was 18%[.] I used their LAA of 25cm and used the highest [mitral regurgitant] jet area I obtained of 4.5 to come to this conclusion. I think the reviewer must have used a jet taken from the [two chamber] view and divided it by a smaller LAA taken from the [four chamber] views which is not kosher.

Dr. Strahan, however, concluded that there was a reasonable medical basis for the attesting physician's finding of an abnormal left atrial dimension.

Based on the auditing cardiologist's diagnosis of mild mitral regurgitation, the Trust issued a post-audit determination denying Ms. Saul's claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.⁵ In contest, claimant submitted an expert opinion by Sheldon E. Litwin, M.D., in which he opined that claimant had moderate mitral regurgitation. Specifically, Dr. Litwin stated that:

The largest mitral regurgitation jet measured 5.59 cm². Compared to the LA size (25.3

5. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms. Saul's claim.

cm²), this calculates as 22% of the LA area. Thus the [mitral regurgitation] would be considered as moderate based on the Singh grading system. The [mitral regurgitation] was measured in the apical 2 chamber and apical long axis views (~5:44 on the tape). Of note, the MR jet and the LA area were measured in the same view. This seems to be appropriate based on the Singh criteria and other currently accepted clinical criteria. If the jet is larger in the 2 chamber or apical long axis view, then this is where it should be measured.... It is also worth noting that my measurement of the MR jet size (5.59 cm²) was slightly, but not greatly larger than that measured by the auditor (4.5 cm²). However, this difference in measurements changes the % area from 18% to 22%. Clinically there is not much difference between 18% and 22%, but by the Singh criteria this should be considered as moderate [mitral regurgitation].

(emphasis in original). Claimant argued that Dr. Litwin's finding of moderate mitral regurgitation provided a reasonable medical basis for her claim.

The Trust then issued a final post-audit determination, again denying Ms. Saul's claim. Claimant disputed this final determination and requested that the claim proceed to the show cause process established by the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807; Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why Ms. Saul's claim should be paid. On May 20, 2005, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 5243 (May 20, 2005).

Once the matter was referred to the Special Master, the Trust submitted its Statement of the Case and Supporting Documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on August 30, 2005. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor⁶ to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Sandra V. Abramson, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor's Report are now before the court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether claimant has met her burden in proving that there is a reasonable medical basis for the attesting physician's finding that she had moderate mitral regurgitation. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant

6. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. U.S., 863 F.2d 149, 158 (1st Cir. 1988). In cases, such as here, where there are conflicting expert opinions, a court may seek the assistance of the Technical Advisor to reconcile such opinions. The use of a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper. Id.

other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement.

See id. Rule 38(b).

In support of her claim, Ms. Saul reasserts the arguments made in contest. In response, the Trust argues that Drs. Smith and Litwin's findings of moderate mitral regurgitation are based on inaccurate measurements. The Trust also asserts that, in audit, Dr. Strahan could not find an RJA/LAA ratio that appeared in the same view which resulted in a ratio greater than 20%.

The Technical Advisor, Dr. Abramson, reviewed claimant's echocardiogram and concluded that there was a reasonable medical basis for the attesting physician's finding of moderate mitral regurgitation. In particular, Dr. Abramson determined that:

In reviewing the transthoracic echocardiogram from 5/31/02, my visual estimate was that the regurgitation could possibly be read as moderate. I measured the mitral regurgitant jet and the left atrial area in the same frame in several representative cycles in the apical views. I calculated the RJA/LAA ratios for these representative cycles and, based on my calculations, I concluded that it would not be unreasonable to assess this amount of mitral regurgitation as moderate.

After reviewing the entire Show Cause Record before us, we find that claimant has established a reasonable medical basis for her claim. Claimant's attesting physician, Dr. Saul, and her

expert, Dr. Litwin, each reviewed claimant's echocardiogram and found moderate mitral regurgitation. Although the Trust contested Drs. Saul and Litwin's conclusions, Dr. Abramson confirmed their findings.⁷ Specifically, Dr. Abramson concluded that "it would not be unreasonable to assess [claimant's] amount of mitral regurgitation as moderate."

As stated above, moderate or greater mitral regurgitation is present where the RJA in any apical view is equal to or greater than 20% of the LAA. See Settlement Agreement § I.22. Here, Drs. Smith and Litwin found moderate mitral regurgitation in the apical view of claimant's echocardiogram, and Dr. Abramson found that it was not unreasonable to assess the level of claimant's mitral regurgitation as moderate. Under these circumstances, claimant has met her burden in establishing a reasonable medical basis for her claim.

For the foregoing reasons, we conclude that claimant has met her burden in proving that there is a reasonable medical basis for her claim and is consequently entitled to Matrix A-1, Level II benefits. Therefore, we will reverse the Trust's denial of the claim submitted by Ms. Saul for Matrix Benefits.

7. Despite an opportunity to do so, the Trust did not submit a response to the Technical Advisor Report. See Audit Rule 34.